

Appl. No. 10/666,301
Amdt dated Jun. 27, 2005
Reply to Office Action of Jan. 26, 2005

Remarks

Amendments to the claims

Claims 26, 30-34, 36-38, 40 and 44-45 remain in this application. Claims 46-79 are new. Claims 1-25, 27-29, 35, 39 and 41-43 are presently canceled without prejudice.

All claims remaining in this application have been amended so as to ensure more consistent use of antecedents. In addition, claims 31-32 and 37-38 have been amended in order to recite applicant's invention using more structural language. These claims have not been amended in order to define patentably over the prior art. Claims 26 and 40 have been amended in order to better clarify applicant's invention and to define patentably over the prior art. All of these amendments are fully supported by the specification and are believed to place this application in condition for allowance.

The rejection of claims 1-9, 12-15, 20-25 and 39 in view of West et al. overcome

The last office action stated that "Claims 1-9, 12-15, 20-25 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. patent No. 5,545,200 to West et al." Claims 1-9, 12-15, 20-25 and 39 are presently canceled without prejudice. Applicant respectfully submits that the Examiner's earlier rejection is moot in light of the cancellation of these claims. Applicant has added new claims 51-75 to this application, these new claims containing subject matter similar to matter previously recited in the aforementioned cancelled claims. Thus, applicant will present discuss the patentability of these new claims over the reference cited by the Examiner in rejection of the originally presented claims. Prior to discussing the arguments for patentability, applicant will first discuss the reference and the general novelty of the present invention and its unobviousness over the reference cited.

Appl. No. 10/666,301
Amdt dated Jun. 27, 2005
Reply to Office Action of Jan. 26, 2005

West et al. disclose a steerable electrophysiology catheter to be used, for example, in cardiac procedures such as cardiac ablation and mapping of cardiac conduction patterns. The device described by West et al. comprises an elongate member and a distal tip secured to the elongate member, wherein the distal tip comprises at least one electrode and wherein a shape of the distal tip is adjustable without removing the catheter from the patient. West et al.'s device "facilitates selective adjustment of the curvature of the distal tip" and allows for "adjustment of the curvature of the deflectable tip without removing the catheter from the patient" (Column 2, lines 61-66). Thus, West et al. do not describe a device manufactured with a desired curve shape with no means for selecting a desired curvature without removing the device from the patient's body. In fact, West et al. teach away from such a device, saying, for example, that prior art catheters suffer from certain disadvantages, including the inability to "select a desired curvature of deflection in the distal tip" (Column 2, lines 41-42). In addition, West et al. do not disclose a device comprising a pressure sensing mechanism for determining a position of the device within a patient's body.

Independent claim 51 recites a device "comprising a portion manufactured to have a desired curve shape", as described in the preferred embodiment of this application (see, for example, paragraphs [0033] and [0037] of applicant's specification). As has been mentioned, not only does the disclosure of West et al. not suggest such a device, it in fact teaches away from such a device. In describing the limitations of prior art devices, West et al., at Column 2, lines 41-42, state as follows: "One such disadvantage is the inability to select a desired curvature of deflection in the distal tip". West et al. also expressly state that a desired curvature should be achievable "without removing the catheter from the patient" (Column 2, lines 65-66). Thus, West et al. clearly teach away from a device that does not enable a user to "select a desired curvature of deflection". The device claimed by applicant comprises a portion manufactured to have a desired

Appl. No. 10/666,301
Amdt dated Jun. 27, 2005
Reply to Office Action of Jan. 26, 2005

curve shape and does not allow a user to "select a desired curvature". Therefore, applicant submits that the device as presently claimed is patentable over the West et al. reference.

Claims 52-75 are dependent from, and incorporate all of the limitations of, independent claim 51 and should therefore be allowable at least for this reason. In addition, claims 52-75 describe new and useful elements of applicant's invention and are believed to be patentable on their own merits.

Claim 55 states that "said proximal region comprises a marking indicative of the orientation of said curved portion". In the last Office Action, the Examiner noted (Paragraph 2(c)): "West et al. further disclose 'wherein the proximal region comprises a marking indicative of the orientation of the curved shape' (See West et al., Figure 4, References 40, 42, and 44; See also Column 8, Lines 29-32)". Applicant respectfully disagrees. The passage cited by the Examiner states as follows: "A handle 38 is secured to proximal end 26 of shaft 22. Handle 38 includes a tip deflection slide 40, core wire torquer ring 42 and curvature adjustment slide 44, as well as an electrical connector 46, all described more fully below." (Emphasis added). West et al. provides a more detailed description of the components of handle 38 in Columns 10 and 11. West et al. describes, in detail, a mechanism by which the curvature of the distal tip may be adjusted. However, nowhere does West et al. indicate that there is any sort of marking present on the catheter body or handle "indicative of the orientation" of the curved portion as claimed by applicant. In fact, applicant respectfully suggests that it would be difficult to include such a marker in West et al.'s device due to the fact that the distal tip, as described by West et al., can be adjusted to many varied orientations using the steering mechanism disclosed therein. It would be inherently difficult to include an orientation marker in this case simply because the adjustable curve can be manipulated to take on so many different orientations. Therefore, in addition to being patentable due

Appl. No. 10/666,301
Amdt dated Jun. 27, 2005
Reply to Office Action of Jan. 26, 2005

to the inclusion of the aforementioned "manufactured to have a desired curve shape" limitation in independent claim 51, claim 55 is believed to be separately patentable on its own merits.

Claim 70 states that applicant's claimed device "is structured such that a first electrode is coupled to a first electric pole and a second electrode is coupled to a second electric pole when said device is connected to an energy source, whereby electrical current flows between said first electrode and said second electrode when energy is delivered to said device." Applicant respectfully submits that West et al. does not teach or even suggest a device structured to connect two electrodes to two separate electrical poles such that electrical current will flow between the electrodes, as claimed by applicant. In fact, West et al. himself suggests (see Column 12, Lines 62-65) that all of the electrodes on West et al.'s device are connected to the same electrical pole: "radiofrequency current is delivered through connector 46 and electrode wires 74 to electrodes 34, 36 through which is current is conducted to the heart tissue to perform ablation". (Emphasis added). Thus, West et al. does not disclose a device comprising multiple electrodes, "such that a first electrode is coupled to a first electric pole and a second electrode is coupled to a second electric pole when said device is connected to an energy source, whereby electrical current flows between said first electrode and said second electrode when energy is delivered to said device" as claimed by applicant.

The rejection of claim 10 in view of West et al. and Edwards et al. overcome

The last office action stated that "Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,545,200 to West et al. as applied to Claim 5 above and in view of U.S. Patent No. 6,635,222 to Edwards et al." Claim 10 has been cancelled without prejudice. New claim 57 incorporates the subject matter of presently

cancelled claim 10. Thus, applicant will presently discuss the patentability of new claim 57 with respect to the Examiner's earlier rejection of claim 10.

Edwards et al. describes a tissue ablation apparatus wherein the RF electrodes each comprise a "tissue piercing distal portion" (Abstract). Edwards et al. further disclose that the electrodes are in non-deployed positions while retained in the delivery catheter and become distended in a deployed state. According to Edwards' specification, this functionality is achieved "by a variety of methods including but not limited to, (i) the electrodes are pre-sprung, confined in delivery catheter and only become sprung (expanded) as they are released from delivery catheter, (ii) the electrodes are made of a memory metal, as explained in further detail below, (iii) the electrodes are made of a selectable electrode material which gives them an expanded shape outside of delivery catheter, or (iv) delivery catheter includes guide tubes which serve to confine electrodes within delivery catheter and guide their direction of travel outside of the catheter" (Column 7, line 65 – Column 8, line 8). In all of the embodiments disclosed by Edwards et al. the electrodes are manufactured of a metallic, electrically conductive material. In addition, due to the inherent stiffness of these materials, the deployment of the electrodes to their distended configurations requires some means of facilitating deployment. Edwards et al. discloses the following means for facilitating deployment of the electrodes: (a) the electrodes are deployed using a 'spring-like mechanism' and use their inherent strength to fan out within the tissue – "The extent of electrode fan like travel is dependent on the strength of the material from which it is made" (Column 9, lines 5-22); (b), the electrodes are heat-treated in order to cause the electrodes to deflect (Column 9, lines 27-32); (c), the electrodes are steerable (Column 9, lines 37-41); and (d), the delivery catheter comprises one or more guide tubes "which serve to direct the expansion of electrodes in the fan pattern as they are advanced out of distal end of the delivery catheter" (Column 9, lines 42-49).

Appl. No. 10/666,301
Amdt dated Jun. 27, 2005
Reply to Office Action of Jan. 26, 2005

Applicant acknowledges that the device disclosed by Edwards et al. does comprise a sharp tip at the distal end of the device. However, applicant respectfully disagrees with the Examiner regarding the suggested combination of Edwards et al. and West et al. As mentioned above, West et al. teaches a steerable EP ablation catheter, which is "transluminally positioned through a blood vessel so that the deflectable tip is within the heart." (Column 12, lines 48-50). Thus, West et al. describes the insertion of his device, as is typical of cardiac ablation devices, through blood vessel lumens into a patient's heart. Applicant respectfully suggests that West et al. does not require, and would not benefit from, a device with a sharp tip since West et al. does not require puncturing tissue in order to enter the heart. In contrast, Edwards et al. describes a tumor ablation device whereby the electrodes are required to pierce the tissue, for example the liver, in order to ablate the tumor. In fact, West et al.'s disclosed application teaches away from this suggested combination, as having a sharp tip is contraindicated due to the fact that it could potentially cause damage to the blood vessel through which the device is inserted and/or to the ablation site within the heart. Thus, applicant submits that these two references should not be combined to render this claim obvious, as per **MPEP § 2143.01**.

One of the novel features of applicant's invention relates directly to this point – that it is possible to have a device with a sharp tip and still ensure that inadvertent damage to cardiac structures is minimized by manufacturing the device with a desired curve shape. However, as is well known, any suggestion to combine references from the prior art cannot come from the applicants themselves. For example, as was stated in Uniroyal, Inc. v. Rudkin-Wiley Corp., 5 U.S.P.Q.2d 1434 (C.A.F.C. 1988): "[w]here prior-art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination *other than the hindsight gleaned from the invention itself*" [Emphasis added].

Even if West et al. and Edwards were to be combined in the manner proposed, the proposed combination would not show all of the novel features recited in the claims, as detailed herein:

Claim 57 is dependent upon claim 51, which recites the limitations that the electrosurgical device comprises "a portion manufactured to have a desired curve shape", "wherein the curved portion is sufficiently pliable so as to conform to a first shape while constrained and to assume said desired curve shape when unconstrained, wherein said first shape and said desired curve shape differ". West et al. does not teach or even suggest a device with the claimed limitations, as has already been discussed. As described above, Edwards et al. discloses a device having electrodes that are in non-deployed positions while retained in the delivery catheter and become distended in a deployed state. However, none of the embodiments described by Edwards et al. comprise a device with a pliable portion manufactured to have a desired curve shape. In one embodiment, the electrodes disclosed by Edwards et al. do not have a manufactured curve shape. Rather, the electrodes comprise a 'spring-like mechanism' which allows them to fan-out, using their inherent strength, when advanced into tissue. However, the extent of their deployment will vary based on the material used and the tissue into which they are inserted – the electrodes do not deploy into any single pre-determined configuration. In a second embodiment, Edwards et al. describe electrodes made of a memory metal, such as nickel titanium. In this embodiment, the electrodes are not manufactured of a pliable polymeric material and require heat treatment in order to assume their intended shape. Thus, the electrodes do not assume a desired curve shape when unconstrained. Rather, the shape is assumed only after heat treatment has been applied. In a third embodiment disclosed by Edwards et al., the electrodes are steerable and, once again, are not manufactured to have a desired curve shape. Finally, in a fourth embodiment, Edwards et al. describes the use of guide tubes in order to direct the electrodes in a desired orientation. This embodiment also

Appl. No. 10/666,301
Amdt dated Jun. 27, 2005
Reply to Office Action of Jan. 26, 2005

does not teach or suggest a device with a manufactured curve portion, whereby the device assumes the desired curve shape when unconstrained. Rather, the electrodes in this embodiment are not necessarily manufactured to have a specific, desired shape but are rather guided in a specified direction using guide tubes placed in a catheter. Thus, none of the embodiments described by Edwards et al. teach or even suggest a device as claimed by applicant.

Thus, even if West et al. and Edwards were to be combined in the manner suggested by the examiner, they still would not teach all of the elements claimed by applicant. Therefore, for all of the reasons mentioned above, applicant submits that claim 58 is in condition for allowance.

The rejection of claim 11 in view of West et al. overcome

The last office action stated that "Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,545,200 to West et al. In regard to claim 11, the selection of a known material based upon its suitability for its intended use is considered an obvious design consideration not patentably distinct over the prior art. (See MPEP, 2144.07)." Applicant has presently cancelled claim 11 without prejudice. New claim 58 contains the limitations previously recited in claim 11. New claim 58 is dependent from claim 57 and includes all limitations thereof. As described above, claim 57 is patentably distinct from the references cited by the Examiner and claim 58 should therefore be allowable at least for this reason.

In addition, claim 58 is further dependent from independent claim 51 which recites the limitations that the electrosurgical device comprises "a portion manufactured to have a desired curve shape" "wherein the curved portion is sufficiently pliable so as to conform to a first shape while constrained and to assume said desired curve shape when

Appl. No. 10/666,301
Amdt dated Jun. 27, 2005
Reply to Office Action of Jan. 26, 2005

unconstrained, wherein said first shape and said desired curve shape differ". As described above, West et al. does not teach or even suggest a device as claimed by applicant, comprising a pliable manufactured curve. As has been mentioned, West et al. describes a steerable catheter, one whose shape may be controlled dynamically. West et al. does not teach or even suggest a catheter comprising a portion manufactured to have a desired curve shape, wherein the curved portion is pliable enough so as to conform to a first shape while constrained and to assume its desired curved shape when unconstrained. Thus, West et al. does not anticipate nor make obvious such a device as claimed by applicant.

Rejection of claims 16-19 and 26-38 in view of West et al. and Maguire et al. overcome

The last office action stated that "Claims 16-19 and 26-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,545,200 to West et al. in view of U.S. Patent Application Publication No. US 2002/0087156 to Maguire et al.". Claims 16-19, 27-29 and 35 have been cancelled without prejudice. Claims 37 and 38 have been amended in order to recite applicant's invention using more structural language. Additionally, claim 26 has been amended to define patentably over these references. Prior to discussing the arguments for patentability, applicant will first discuss the references applied and the general arguments against the combination of these two references as suggested by the Examiner.

West et al. has already been described above.

Maguire et al. discloses a method of manufacturing a tissue ablation catheter comprising a balloon to which a sensor is attached. Maguire et al. further discloses that his device incorporates "fluid pressure monitoring" (Paragraphs [0286] – [0290])

whereby the "fluid pressure at various locations in the patient's body can also be used to establish the position of the ablation catheter" (Paragraph [0287], Lines 1-3) either by using a pressure transducer or by using a fluid filled lumen. More specifically, Maguire et al. describes using fluid pressure measurements proximal and distal to the expandable balloon (Paragraphs [0289] and [0290]) in order to establish whether or not the balloon "is properly seated in the ostium" (Paragraph [0289], Line 16). In other words, the specified purpose of Maguire et al.'s "fluid pressure monitoring" system is not to specifically determine where in the body the catheter is located but is rather to establish the position of the ablation catheter within the vein. In other words, fluid pressure measurements made using a fluid-filled lumen are useful to ascertain whether or not the balloon of the ablation catheter has expanded properly to fill the vein's lumen.

Objection to the combination of West et al. and Maguire et al.

Regarding a motivation to combine these references, the Examiner noted (Paragraphs 6(a), (d) and (e) of the last Office Action) with respect to claims 16, 19 and 26, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a pressure sensing mechanism/pressure transducer as taught by Maguire et al. on the device disclosed by West et al. "in order to monitor pressure about the distal region in order to establish/monitor the position of the ablation catheter within the patient". West et al.'s device is an ablation catheter used to deliver energy to a specific and precise location of a patient's heart. Applicant acknowledges that West et al. would benefit from a precise localization means that would allow a user to precisely determine the location of the catheter relative to a desired ablation and/or mapping site. However, applicant respectfully suggests that a pressure sensing mechanism would not provide these benefits, but would rather provide only a general location of the device within a patient's body. West et al.'s device is individually complete and would not benefit from a pressure sensor to determine the general location of the device within the

Appl. No. 10/666,301
Amdt. dated Jun. 27, 2005
Reply to Office Action of Jan. 26, 2005

patient. There is no suggestion in either West et al. or Maguire et al., explicit or implied, that these references be combined. Thus, applicant contends that there is a lack of motivation to combine Maguire et al. and West et al. in the manner suggested by the Examiner. MPEP § 706.02(j) states, in part, that in order to establish a *prima facie* case of obviousness, "there must be some suggestion of motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings." Applicant respectfully suggests that, absent some specific rationale in West et al., there would be no motivation for one skilled in the art of the present invention to incorporate a pressure sensing lumen into the device described therein. As has been mentioned, pressure sensing mechanisms do not provide precise localization information and would add bulkiness (especially in the case of a lumen) to devices incorporating such mechanisms. In addition, to the best of applicant's knowledge, no ablation catheters are currently sold with pressure sensing lumens since, presumably, incorporating such lumens would seem to be of limited benefit.

Even if West et al. and Maguire et al. were to be combined in the manner suggested, the proposed combination would not show all of the novel features recited in the claims, as detailed herein:

Independent claim 26 has been amended to recite the limitation that the device comprises "a portion manufactured to have a desired curve shape, such that said functional tip is automatically directed in a desired direction after perforating an interatrial septum". Neither West et al. nor Maguire et al. nor any combination thereof teach or even suggest a device with the aforementioned limitation. Thus, even if West et al. and Maguire et al. were to be combined in the manner suggested by the examiner, they still would not teach all of the elements claimed by applicant. A further condition for establishing obviousness is that "the prior art reference (or references when

Appl. No. 10/666,301
Amdt dated Jun. 27, 2005
Reply to Office Action of Jan. 26, 2005

combined) must teach or suggest all the claim limitations." Applicant believes that there is no suggestion or motivation to combine the teachings of Jain and Maguire et al. and that, even if they were to be combined, the resulting device would not anticipate the device as claimed in the present invention. Therefore, applicant respectfully requests that this rejection be reconsidered.

Claims 30-34 and 36-38 are dependent from claim 26 and should be allowable at least for this reason. In accordance with the Examiner's rejections, claims 37 and 38 have been amended in order to recite applicant's invention using more structural language. In addition, claims 30-34 and 36-38 have been amended in order to ensure consistent use of proper antecedent language. All of the amendments described herein are fully supported by applicant's specification as filed.

Rejection of claim 36 in view of West et al. and Maguire et al. overcome

The Examiner has rejected **claim 36** as being obvious based on West et al. in view of Maguire et al. Specifically, the Examiner stated that West et al. discloses "wherein the electrical energy source is capable of providing high-frequency electrical energy to the functional tip in the high-impedance range (See West et al., Column 12, Lines 61-65)". In addition to the arguments presented above regarding the combination of West et al. and Maguire et al., applicant respectfully traverses this rejection. Ablation catheters generally have larger electrodes than perforation catheters (such as the device claimed by applicant) and are therefore operated in a lower impedance range than perforation catheters. Applicant directs the Examiner's attention to two references submitted to the Examiner, entitled "Radio frequency perforation of cardiac tissue: modelling and experimental results" by Shimko et al. and "Radio Frequency Perforation System" by Baylis Medical Company Inc. Both of these references describe the differences between systems (generators and energy delivery devices) used for Cardiac Ablation

Appl. No. 10/666,301
Amdt dated Jun. 27, 2005
Reply to Office Action of Jan. 26, 2005

vs. Cardiac Perforation. In addition, applicant's specification states (Paragraph [0036], Lines 1-8): "The generator 122 is preferably a radiofrequency (RF) electrical generator that is designed to work in a high impedance range. Because of the small size of functional tip 108, impedance encountered during RF energy application is very high. General electrosurgical generators are typically not designed to deliver energy in this impedance range, so only certain RF generators can be used with this transseptal device 100". West et al. does not disclose anywhere that his electrical power source is anything but a "general electrosurgical generator" which, as noted in applicant's specification, "are typically not designed to deliver energy in this (high) impedance range".

Applicant notes that Shah et al., in a reference cited by the Examiner, at Column 3, lines 33-36, reads as follows: "The generator like existing radio frequency generators is a voltage generating means connected to an electrically conductive guidewire to activate the un-insulated distal tip in a monopolar fashion." (Emphasis added). Applicant suggests that this disclosure does not in any way imply that a generator capable of radio frequency perforation is identical to existing radio frequency generators. Rather, Shah et al. describe that the perforation generator is similar to existing RF generators (for example, cardiac ablation generators) in that they all share the common characteristics listed in the cited sentence, namely being "voltage generating means connected to an electrically conductive guidewire to activate the un-insulated distal tip in a monopolar fashion". This does not suggest that cardiac ablation generators share other characteristics with perforation generators, namely that they are "capable" of providing energy in a high-impedance range.

Furthermore, the reference entitled "Radio Frequency Perforation System", on page 5, shows a comparison of Ablation and Perforation generator power curves illustrating the different impedance ranges over which the respective generators operate. In addition,

Appl. No. 10/666,301
Amdt dated Jun. 27, 2005
Reply to Office Action of Jan. 26, 2005

the associated text reads "The BMC Perforation Generator is unlike cardiac ablation generators. It delivers high voltage energy and functions in a high impedance range to create the desired perforation." (Emphasis added). Thus, applicant suggests that, absence evidence to the contrary, the electrical energy source disclosed by West et al. for use in cardiac ablation procedures would not be understood, by one skilled in the art at the time of the invention, to be capable of providing a high-frequency electrical power to said functional tip in a high impedance range.

The rejection of claims 40-43 and 45 in view of Shah et al. and West et al. overcome

The last office action stated that "Claims 40-43 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,565,562 to Shah et al. in view of U.S. Patent No. 5,545,200 to West et al.". Claims 41-43 are presently cancelled without prejudice. Claim 40 has been amended in order to define patentably over the prior art. Thus, applicant respectfully traverses this rejection for reasons that will be presently described.

Statement of Common Ownership

Prior to presenting arguments related to the combination of these references, applicant submits that the present U.S. Patent Application, serial number 10/666,301, and U.S. Patent No. 6,565,562 to Shah et al. were, at the time the invention of Application No. 10/666,301 was made, commonly owned by Baylis Medical Company Inc. Thus, it is applicant's understanding that the Shah et al. reference does not qualify as 35 U.S.C. 103(a) prior art as per 35 U.S.C. 103(c) and MPEP 706.02(I).

Appl. No. 10/666,301
Amdt dated Jun. 27, 2005
Reply to Office Action of Jan. 26, 2005

Even if Shah et al. and West et al. were to be combined in the manner proposed, the proposed combination would not show all of the novel features recited in the claims, as detailed herein:

Independent claim 40 has been amended to recite the limitation that "said distal region comprises a portion manufactured to have a desired curve shape; and advancing a distal tip of the device through the septum such that said distal tip is automatically directed away from cardiac structures while being advanced, due to a shape of the curved portion". Neither Shah et al. nor West et al. nor any combination thereof teach or even suggest a method of creating a perforation using a device with the aforementioned limitation, namely a portion manufactured to have a desired curve shape. In addition, neither Shah et al. nor West et al. nor any combination thereof teach or even suggest a method of use comprising a step of "advancing a distal tip of the device through the septum such that said distal tip is automatically directed away from cardiac structures while being advanced, due to a shape of the curved portion". In the last Office Action (Paragraph 7(d)), the Examiner noted, with reference to Shah et al., that "when distal tip is directed at the septum it is 'directed away from cardiac structures in order to decrease risk of unwanted injury' ". Applicant has amended claim 40 to recite that the distal tip is directed away from cardiac structures "while being advanced, due to a shape of the curved portion". Applicant respectfully submits that neither Shah et al. nor West et al. nor any combination thereof teaches or even suggests such a limitation. Thus, even if Shah et al. and West et al. were to be combined in the manner suggested by the examiner, they still would not teach all of the elements claimed by applicant.

Appl. No. 10/666,301
Amdt dated Jun. 27, 2005
Reply to Office Action of Jan. 26, 2005

Claim 45 is dependent from independent claim 40 and should therefore be allowable at least for this reason. In addition, claim 45 is itself patentable on its own merits as will be presently described.

Rejection of claim 45 in view of Shah et al. and West et al. overcome

The last Office Action stated, regarding claim 45, that "West et al. further disclose 'wherein the perforation device comprises an orientation indicator for determining a direction of the distal tip' (See West et al., Figure 4, References 40, 42 and 44)." Applicant respectfully traverses this rejection.

West et al., Column 8, lines 29-32, states as follows: "A handle 38 is secured to proximal end 26 of shaft 22. Handle 38 includes a tip deflection slide 40, core wire torquer ring 42 and curvature adjustment slide 44, as well as an electrical connector 46, all described more fully below." (Emphasis added). West et al. provides a more detailed description of the components of handle 38 in Columns 10 and 11. West et al. describes, in detail, a mechanism by which the curvature of the distal tip may be adjusted. However, nowhere does West et al. indicate that there is any sort of marking or indicator present on the catheter body or handle "indicative of the orientation" of the curved portion as claimed by applicant. In fact, applicant respectfully suggests that it would be difficult to include such a marker in West et al.'s device due to the fact that the distal tip, as described by West et al., can be adjusted to many varied orientations using the steering mechanism disclosed therein. It would be inherently difficult to include an orientation marker in this case simply because the adjustable curve can be manipulated to take on so many different orientations. Therefore, in addition to being patentable due to the inclusion of the aforementioned "manufactured to have a desired curve shape" limitation in independent claim 40, claim 45 is believed to be separately patentable on its own merits.

Appl. No. 10/666,301
Amdt dated Jun. 27, 2005
Reply to Office Action of Jan. 26, 2005

The rejection of claim 44 in view of West et al., Shah et al. and Maguire et al. overcome

The last Office Action stated: "Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,545,200 to West et al. in view of U.S. Patent No. 6,565,562 to Shah et al. as applied to Claim 40 above and in further view of U.S. Patent Application Publication No. US 2002/0087156 to Maguire et al." Applicant respectfully traverses this rejection.

As has been previously mentioned, applicant submits that the Shah et al. reference does not qualify as prior art under 35 U.S.C. 103(a) due to common ownership of Shah et al. and the instant application as per 35 U.S.C. 103(c). In addition, applicant objects to the combination of West et al./Shah et al. with Maguire et al. As has been mentioned, West et al.'s device is an ablation catheter used to deliver energy to a specific and precise location of a patient's heart. Shah et al.'s device is a perforation catheter used to perforate tissue at a specific location in a patient's body. Applicant acknowledges that both West et al. as well as Shah et al. would benefit from a precise localization means that would allow a user to precisely determine the location of the catheter relative to a desired ablation and/or perforation site. However, applicant respectfully suggests that a pressure sensing mechanism would not provide these benefits, but would rather provide only a general location of the device within a patient's body. There is no suggestion in West et al., Shah et al. or Maguire et al., explicit or implied, that these references be combined. Thus, applicant contends that there is a lack of motivation to combine Maguire et al. and West et al./Shah et al. in the manner suggested by the Examiner. Applicant respectfully suggests that, absent some specific rationale in West et al. or Shah et al., there would be no motivation for one skilled in the art of the present invention to incorporate a pressure sensing lumen into the device

Appl. No. 10/666,301
Amdt dated Jun. 27, 2005
Reply to Office Action of Jan. 26, 2005

described therein. As has been mentioned, pressure sensing mechanisms do not provide precise localization information and would add bulkiness (especially in the case of pressure sensing lumens) to devices incorporating such mechanisms.

Even if West et al., Shah et al. and Maguire et al. were to be combined in the manner suggested, the proposed combination would not show all of the novel features recited in the claims, as detailed herein:

Claim 44 depends from independent claim 40. As described above, claim 40 has been amended to recite the limitation that "said distal region comprises a portion manufactured to have a desired curve shape; and advancing a distal tip of the device through the septum such that said distal tip is automatically directed away from cardiac structures while being advanced, due to a shape of the curved portion". Neither Shah et al. nor West et al. nor Maguire et al. nor any combination thereof teach or even suggest a method of creating a perforation using a device with the aforementioned limitation, namely a portion manufactured to have a desired curve shape. In addition, neither Shah et al. nor West et al. nor Maguire et al. nor any combination thereof teach or even suggest a method of use comprising a step of "advancing a distal tip of the device through the septum such that said distal tip is automatically directed away from cardiac structures while being advanced, due to a shape of the curved portion". Claim 44 is dependent from, and incorporates the limitations of, claim 40. Thus, even if Shah et al., West et al. and Maguire et al. were to be combined in the manner suggested by the examiner, they still would not teach all of the elements as claimed by applicant.

New claims

Appl. No. 10/666,301
Amdt dated Jun. 27, 2005
Reply to Office Action of Jan. 26, 2005

Claims 46-79 have been added to this application. All new claims are supported by applicant's specification as originally filed and include patentable features not disclosed or taught by the cited references, alone or in combination.

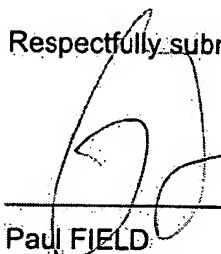
Conclusion

As each claim remaining herein is directed to allowable subject matter, Applicant submits the amendment puts the application in condition for allowance and a Notice of Allowance is requested.

Applicant advises its present amendment is directed to expediting the issuance of this allowable subject matter and is not to be construed as surrendering any subject matter in the amended or canceled claims or as an admission that such claims prior to this amendment are not patentable. Thus, all currently canceled claims are canceled without prejudice.

If the Examiner believes there are any further matters which need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

Respectfully submitted,



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Appl. No. 10/666,301
Amdt. dated Jun. 27, 2005
Reply to Office Action of Jan. 26, 2005

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